General

Guideline Title

Ivabradine for treating chronic heart failure.

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Ivabradine for treating chronic heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Nov. 49 p. (Technology appraisal guidance; no. 267).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Ivabradine is recommended as an option for treating chronic heart failure for people:

- With New York Heart Association (NYHA) class II to IV stable chronic heart failure with systolic dysfunction and
- Who are in sinus rhythm with a heart rate of 75 beats per minute (bpm) or more and
- Who are given ivabradine in combination with standard therapy including beta-blocker therapy, angiotensin-converting enzyme (ACE) inhibitors and aldosterone antagonists, or when beta-blocker therapy is contraindicated or not tolerated and
- With a left ventricular ejection fraction of 35% or less.

Ivabradine should only be initiated after a stabilisation period of 4 weeks on optimised standard therapy with ACE inhibitors, beta-blockers and aldosterone antagonists.

Ivabradine should be initiated by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be carried out by a heart failure specialist, or in primary care by either a general practitioner (GP) with a special interest in heart failure or a heart failure specialist nurse.

Clinical Algorithm(s)

A National Institute for Health and Clinical Excellence (NICE) Pathway for chronic health failure is available on the NICE Web site .

Scope

Disease/Condition(s)

Chronic heart failure

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Cardiology

Family Practice

Geriatrics

Internal Medicine

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of ivabradine for treating chronic heart failure

Target Population

People with chronic heart failure New York Heart Association (NYHA) class II to IV with systolic dysfunction, in sinus rhythm and whose heart rate is 75 beats per minute (bpm) or more, who are being treated with ivabradine in combination with standard therapy including beta-blockers, or for whom beta-blockers are contraindicated or not tolerated

Interventions and Practices Considered

Ivabradine

Major Outcomes Considered

- Clinical effectiveness
    - Composite of first event of cardiovascular death or hospitalisation for worsening heart failure (HF)

- Death from any cause
- Death from HF
- Hospitalisation for cardiovascular reason (including hospitalisation for undetermined cause)
- Hospitalisation for any cause
- Unplanned hospitalisation for any cause
- Unplanned hospitalisation for cardiovascular reason
- Adverse effects of treatment
- Health-related quality of life

- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by British Medical Journal (BMJ) Technology Assessments Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description and Discussion of Appropriateness of Manufacturer's Search Strategy

The manufacturer's submission (MS) gave detailed descriptions of the search terms and strategies used to identify relevant studies assessing the clinical effectiveness and cost effectiveness of ivabradine in the treatment of patients with chronic heart failure. Initially, the manufacturer searched the literature up to May 2011 and subsequently carried out a second literature review to update the results from that date to January 2012 to ensure that all studies relevant to the decision problem were identified. The Evidence Review Group (ERG) noted minor differences between the search terms and strategies used for the initial and update reviews. The manufacturer helpfully reported that the literature search carried out in May 2011 was performed in EMBASE.com (EMBASE and Medline databases) and the Cochrane Library, whereas the update search was carried out via OVID [EMBASE, MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE(R)] and in the Cochrane Library. The manufacturer clarified that the original systematic review did not search MEDLINE(R) In-Process, and thus it was necessary to develop the search strategy for the update systematic review. The ERG considers the manufacturer's approach to be appropriate.

The manufacturer listed the specific databases searched, the time period covered by the search, and the date the searches were run. The manufacturer supplemented the search by searching the US National Institutes of Health clinical trials registry (ClinicalTrials.gov) and the Australian New Zealand Clinical Trials Registry (ANZCTR). In addition, to identify Clinical Study Reports (CSRs), the manufacturer searched the Servier Therapeutic Goods Administration dossier for ivabradine as part of the initial systematic review (May 2011). The ERG considers the search strategy used by the manufacturer to be comprehensive, with appropriate search terms. As the manufacturer highlights, the search strategy did not limit the search to randomised controlled trials (RCTs); the search strategies also identified controlled non-RCTs. However, the MS states that only RCTs were included in the assessment on the clinical effectiveness of ivabradine. The manufacturer used multiple search terms for heart failure and ivabradine. It is not clear whether reference lists of identified RCTs were evaluated for additional suitable studies. The manufacturer reports that identified studies were independently assessed by a reviewer to determine whether the study met the pre-defined inclusion criteria, and any uncertainties were resolved by discussion with a second reviewer.

The ERG validated the manufacturer's search strategy via OVID [EMBASE, MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)], and the Cochrane Library (02/05/2012; flow diagram presented in Appendix 2 of the ERG report). The ERG generated fewer studies for screening compared with the manufacturer's search (195 studies screened by the manufacturer versus 159 studies screened by the ERG). The ERG does not have access to EMBASE.com or the manufacturer's in-house database and was therefore unable to replicate the manufacturer's search. The ERG considers the discrepancy in number of studies identified is to be expected. After deduplication of the search results, abstracts and titles were appraised by one reviewer against the inclusion/exclusion criteria used by the manufacturer. Based on the criteria

listed, the ERG identified the full publication of the SHIfT trial, and associated publications; no additional studies in the population of interest relevant to the decision problem and reporting on outcomes specified in the final scope were identified.

Inclusion/Exclusion Criteria Used in Study Selection

Inclusion Criteria

Population: Patients with systolic heart failure

Intervention(s): Ivabradine

Outcomes:

Mortality endpoints:

- All-cause mortality
- Cardiovascular mortality
- Death from heart failure

Morbidity endpoints:

- All-cause hospital admission
- Hospital admission for worsening heart failure
- Any cardiovascular admission

Study design: Randomised, double-blind controlled trials

Language restriction: None

Exclusion Criteria

Population: Patients without systolic heart failure, or population not consistent with ivabradine Summary of Product Characteristics (SPC)

Intervention(s): Studies not including ivabradine

Outcomes: Surrogate outcomes (e.g., change in exercise capacity) rather than the final endpoints of mortality and morbidity

Study design:

- Studies that were not randomised
- Letters
- Commentaries
- Notes
- Editorials
- Reviews
- Methodological papers

Language restriction: None

With reference to the criteria for outcomes, the ERG notes that the manufacturer has not listed health-related quality of life (HRQoL) or adverse effects as criteria for either inclusion or exclusion, both of which are listed as outcomes of interest to the decision problem. During abstract appraisal, the ERG did not exclude studies based on outcome assessed.

The ERG considers that the clinical-effectiveness literature review process, as described in the MS, follows systematic review practices outlined by the Centre for Reviews and Dissemination.

Cost-Effectiveness

Summary and Critique of the Manufacturer's Review of Cost-effectiveness Evidence

The manufacturer stated *a priori* that they did not expect to find evidence within published literature of the cost-effectiveness of ivabradine in patients with heart failure. Therefore, the manufacturer developed a wider search for economic evaluations in heart failure that could be used to inform modelling methods of a *de novo* cost-utility analysis. The manufacturer initially carried out a systematic search in 2011 of: MEDLINE;

MEDLINE(R) In-Process; EMBASE; National Health Service Economic Evaluation Database (NHS-EED); EconLit; and Cochrane databases. In addition, the following Centre for Reviews and Dissemination (CRD) database were searched:

- Health Economic Evaluation Database
- Database of Abstracts of Reviews and Effects
- Health Technology Assessment Database

To ensure that all publications relevant to the decision problem were captured, the manufacturer updated the search to 2012, limiting the period of the search from 2006 to 2012. The restriction applied was intended to exclude all but the most recent and relevant cost-effectiveness studies.

Table 21 of the ERG report (see the "Availability of Companion Documents" field) summarises the pharmacological studies included in the manufacturer's review, which used a Markov framework and a lifetime (or 10-year) time horizon. The manufacturer reported that these studies were used to inform the methods used to develop the *de novo* model that was implemented to assess the relative cost-effectiveness of ivabradine.

Number of Source Documents

Clinical Effectiveness

- One randomised controlled trial (RCT) (8 publications)

Cost-Effectiveness

- Four studies were included in the review to inform the manufacturer's model implemented to assess the relative cost-effectiveness of ivabradine.
- The manufacturer presented an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by British Medical Journal (BMJ) Technology Assessments Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Quality Assessment

The manufacturer assessed the SHIfT trial against criteria adapted from guidance for undertaking reviews in health care issued by the Centre for Reviews and Dissemination, as provided in NICE's template for manufacturer/sponsor submission of evidence to the Single Technology Appraisal (STA) process. The Evidence Review Group (ERG) independently validated SHIfT and agrees with the manufacturer's assessment (see Appendix 3 in the ERG report). The ERG considers SHIfT to be a well-designed RCT.

Summary Statement

The ERG considers that the manufacturer's systematic review followed recommended methodological practices. Moreover, the manufacturer's transparent reporting enabled the ERG to replicate their search results. The submitted clinical evidence is based on a subgroup analysis of one large, multicentre trial (SHIfT). The manufacturer presented a clear overview of the methods of the SHIfT trial. In addition, the manufacturer presented evidence to support the generalisability of the results to UK clinical practice. The SHIfT trial was a well-designed trial with a primary objective of assessing the superiority of ivabradine over placebo in reducing time to first event of cardiovascular death or hospitalisation for worsening heart failure (the primary composite outcome of the trial). The manufacturer presented data for the individual components of the composite outcome, in addition to data on all other outcomes relevant to the decision problem as outlined in the final scope issued by NICE. The ERG notes that the population that is relevant to the decision problem is younger and has more severe heart failure compared with patients typically seen in UK clinical practice, but recognises that the population is similar to those seen in other key trials in heart failure. The ERG considers that the presented analyses can be used to inform the decision problem, but notes that, because data come from numerous subgroup analyses, the results should be interpreted with a degree of caution.

See Section 4 of the ERG report (see the "Availability of Companion Documents" field) for additional information.

Cost Effectiveness

Summary and Critique of Manufacturer's Submitted Economic Evaluation

The manufacturer developed a *de novo* model to evaluate the clinical and economic consequences of adding ivabradine to standard care. The model was constructed in Microsoft© EXCEL and was a two-state Markov cohort model. The manufacturer described this approach as "simple, flexible and consistent with previous approaches taken in cost-effectiveness studies of pharmaceutical interventions in heart failure". The ERG agrees that the modelling approach taken by the manufacturer is reasonable and is consistent with other published economic studies evaluating interventions used in the treatment of heart failure. Furthermore, the ERG notes that the model was well constructed and largely transparent and that patient-level rather than cohort data have been used to improve the accuracy of the model's base case results. However, the ERG considers it important to highlight that an excessive use of coding made it difficult to stress test the model. In addition, the base case and subgroup results took an average of two hours to update.

See Section 5 of the ERG report (see the "Availability of Companion Documents" field) for additional information on cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites "consultee" and "commentator" organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an "assessment report". Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from

nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the "appraisal consultation document" (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the "final appraisal determination" (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions on Cost-Effectiveness

The manufacturer developed a Markov cohort model to evaluate the cost-effectiveness of ivabradine in combination with standard therapy including beta-blockers, or for whom beta-blockers are contraindicated or not tolerated for treating chronic heart failure.

Uncertainties around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee considered the uncertainty around the benefit of ivabradine on cardiovascular mortality given that the incremental cost-effectiveness ratio (ICER) ranged between approximately £5600 and £40,600 per quality-adjusted life-year (QALY) gained when the risk of cardiovascular mortality was varied using the 95% confidence interval around the mean from the trial data, and concluded that the additional treatment effect of ivabradine was uncertain compared with the effect of beta-blocker doses.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values

The Committee was satisfied that the utility values applied in the model were derived from SHiFT, which was the pivotal trial used in the economic analysis, and considered the approach taken by the manufacturer to obtain the final utility estimates to be plausible and robust.

Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee considered that there were no additional gains in health-related quality of life over those already included in the QALY calculations.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost-Effective?

The Committee was aware that the sensitivity analyses conducted by the manufacturer were robust for the base-case estimate, except for the risk of cardiovascular mortality and the ICERs for all the subgroup analyses were below £11,000 per QALY gained.

What Are the Key Drivers of Cost-Effectiveness?

The Committee considered that the effect of ivabradine on the hospital admission endpoints was the key driver of the cost-effectiveness of ivabradine plus standard care compared with standard care alone.

Most Likely Cost-Effectiveness Estimate (Given as an ICER)

The Committee concluded that the manufacturer's ICER estimate of approximately £8500 per QALY gained was plausible and was the most likely cost-effectiveness estimate of ivabradine in addition to standard care for treating chronic heart failure in the population covered by the

marketing authorisation.

See Sections 3 and 4 of the original guideline document for details of the economic analysis provided by the manufacturer, the Evidence Review Group comments, and the Appraisal Committee considerations.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the appraisal consultation document (ACD) and were provided with the opportunity to appeal against the final appraisal determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence and a review of this submission by the Evidence Review Group. For clinical effectiveness, one randomised controlled trial was the main source of evidence. For cost-effectiveness, the manufacturer's model was considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of ivabradine for treating chronic heart failure

Potential Harms

The summary of product characteristics lists the following adverse reactions for ivabradine: luminous phenomena (phosphenes), bradycardia, atrioventricular first degree block, ventricular extrasystoles, blurred vision, headache, dizziness and uncontrolled blood pressure.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

Ivabradine is contraindicated in severe hypotension (less than 90/50 mmHg), for people with unstable heart failure, and in people whose heart rate

is dependent on a pacemaker.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Clinical Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- The Secretary of State and the Welsh Assembly Minister for Health and Social Services have issued directions to the National Health Service (NHS) in England and Wales on implementing National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance. When a NICE technology appraisal recommends use of a drug or treatment, or other technology, the NHS must usually provide funding and resources for it within 3 months of the guidance being published. If the Department of Health issues a variation to the 3-month funding direction, details will be available on the NICE website. When there is no NICE technology appraisal guidance on a drug, treatment or other technology, decisions on funding should be made locally.
- The technology in this appraisal may not be the only treatment for chronic heart failure recommended in NICE guidance, or otherwise available in the NHS. Therefore, if a NICE technology appraisal recommends use of a technology, it is as an option for the treatment of a disease or condition. This means that the technology should be available for a patient who meets the clinical criteria set out in the guidance, subject to the clinical judgement of the treating clinician. The NHS must provide funding and resources (in line with the above section) when the clinician concludes and the patient agrees that the recommended technology is the most appropriate to use, based on a discussion of all available treatments.
- NICE has developed a costing template and report to estimate the national and local savings and costs associated with implementation. It is available on the NICE website .

Implementation Tools

Clinical Algorithm

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Ivabradine for treating chronic heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Nov. 49 p. (Technology appraisal guidance; no. 267).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Nov

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Clinical Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Professor Andrew Stevens (*Chair of Appraisal Committee C*), Professor of Public Health, University of Birmingham; Professor Gary McVeigh (*Vice Chair of Appraisal Committee C*), Professor of Cardiovascular Medicine, Queens University, Belfast and Consultant Physician, Belfast City Hospital; Dr David Black, Director of Public Health, Derbyshire County Primary Care Trust; Dr Daniele Bryden, Consultant in Intensive Care Medicine and Anaesthesia, Sheffield Teaching Hospitals NHS Trust; Dr Andrew Burnett, Director for Health Improvement and Medical Director, NHS Barnet, London; David Chandler, Lay member; Dr Mary Cooke, Lecturer, School of Nursing, Midwifery and Social Work, University of Manchester; Dr Chris Cooper, General Practitioner, St John's Way Medical Centre, London; Professor Peter Crome, Consultant Geriatrician and Professor of Geriatric Medicine, Keele University; Dr Maria Dyban, General Practitioner, Kings Road Surgery, Glasgow; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Dr Greg Fell, Consultant in Public Health, Bradford and Airedale Primary Care Trust; Dr Wasim Hanif, Consultant Physician and Honorary Senior Lecturer, University Hospital Birmingham; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Professor Cathy Jackson, Professor of Primary Care Medicine, University of St Andrews; Dr Peter Jackson, Clinical Pharmacologist, University of

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Ivabradine for treating chronic heart failure. Costing template. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Nov 28. (Technology appraisal; no. 267). Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site .
- Chronic heart failure. NICE pathway. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Nov. (Technology appraisal; no. 267). Electronic copies: Available from the NICE Web site .
- Edwards SJ, Barton S, Nherera L, Trevor N, Hamilton V. Ivabradine for the treatment of chronic heart failure: a single technology appraisal. London (UK): BMJ-TAG; 2012. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site .

Patient Resources

The following is available:

- Ivabradine for chronic heart failure. Information for the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Nov 6 p. (Technology appraisal; no. 267). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 10, 2013.

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